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## WYETH V. LEVINE: MOVING AWAY FROM THE *GEIER* TREND

### INTRODUCTION

Federal preemption of state common law actions for injuries often involves a balancing act between congressional intent and state sovereignty.<sup>1</sup> The existence of federal agencies, such as the FDA, has raised issues concerning the relationship between comprehensive regulatory schemes and the residual role of state laws.<sup>2</sup>

Congress has done little to confront these issues,<sup>3</sup> leading to various interpretations of express preemption provisions. In cases of implied preemption, the Supreme Court has employed the impossibility and obstacle analyses for determining the availability of state common law remedies.<sup>4</sup>

The FDA's recent position establishing its standards as the "ceiling" in safety determinations has triggered a debate between giving preemptive effect to agency interpretations and preserving the presumption against preemption expressed by saving clauses.<sup>5</sup> In *Wyeth v. Levine*,<sup>6</sup> the Supreme Court sought to clarify these issues.

Part I of this Comment provides a general overview of preemption and focuses on the preemption analysis the Court has previously employed with regard to FDA regulations. Part II summarizes the facts and holding in *Wyeth*. Part III analyzes *Wyeth*, commends the Court's holding, but suggests a strict adherence to notice-and-comment rulemaking and an abandonment of the obstacle analysis. This Comment concludes by suggesting a classification of prescription drugs to balance the presumption against preemption with the FDA's safety determinations.

### I. BACKGROUND

#### A. *The Supremacy Clause and the Preemption Doctrine*

The Supremacy Clause states, "This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."<sup>7</sup> The

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1. See Sandra Zellmer, *Preemption by Stealth*, 45 Hous. L. Rev. 1659, 1666 (2009).

2. See Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. Rev. 1089, 1092-93 (2007).

3. See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227, 251 (2007).

4. See Zellmer, *supra* note 1, at 1666.

5. See Davis, *supra* note 2, at 1092-93.

6. 129 S. Ct. 1187 (2009).

7. U.S. CONST. art. VI, cl. 2.

preemption doctrine acts as “a tool for defining the parameters of federal supremacy when Congress has adopted legislation pursuant to other enumerated powers.”<sup>8</sup> These pieces, working together, make clear that the purpose of Congress acts as the ultimate “touch-stone” in every preemption analysis.<sup>9</sup>

Federal preemption can be express or implied.<sup>10</sup> Express preemption occurs where Congress has included an express preemption provision in the statute.<sup>11</sup> Implied preemption arises either through field preemption, “where the federal legislation is so comprehensive that Congress must have intended to occupy the field,” or through conflict preemption, where state and federal laws conflict.<sup>12</sup>

Implied conflict preemption overrides a state law that either creates an impossibility of complying with both federal and state laws (“impossibility analysis”), or “poses an obstacle to the achievement of federal objectives” (“obstacle analysis”).<sup>13</sup>

However, because states have historically held traditional police powers to protect the health, safety, and welfare of their citizens, preemption of state common law remedies is often complex and controversial.<sup>14</sup> Federalism concerns drive a presumption against preemption of state police powers where “a clear manifestation of congressional intent to preempt” state laws and state common law remedies does not exist.<sup>15</sup> Moreover, Congress generally includes a saving clause in its legislation, which statutorily preserves the presumption against preemption.<sup>16</sup>

Absent an express preemption provision in the statute, the Court has employed both the impossibility and the obstacle analyses of implied conflict preemption. In applying the preemption analysis, the U.S. Supreme Court, faced with federal regulations and state concerns, has varied between its reliance on the statutory text and agency explanations in determining the preemptive effect of a federal regulation.<sup>17</sup>

#### *B. Geier v. American Honda Motor Co.*<sup>18</sup>

In *Geier*, the U.S. Supreme Court held that a state tort action was preempted as an obstacle to the achievement of the Federal Motor Vehicle Safety Standard (“FMVSS”) 208.<sup>19</sup> The standard, promulgated by

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8. Zellmer, *supra* note 1, at 1665.

9. *Id.* at 1666.

10. *Id.*

11. *Id.*

12. *Id.*

13. *See id.*

14. *See id.*

15. *Id.* at 1667.

16. *See id.* at 1660.

17. *See Sharkey, supra* note 3, at 258–59.

18. 529 U.S. 861 (2000).

19. *Id.* at 886.

the Department of Transportation within its authority under the National Traffic and Motor Vehicle Safety Act ("Safety Act"), sought a gradual development of various passive restraint systems in cars—notably, the installation of seat belts and airbags.<sup>20</sup> Although the FMVSS was aimed at reducing traffic accidents, it did not mandate a strict airbag standard for all vehicles.<sup>21</sup>

The petitioner suffered injuries from a car crash and brought a common law suit against Honda for not equipping the car with an airbag.<sup>22</sup> The Court held that although the Safety Act did not expressly preempt the "no airbag" suit,<sup>23</sup> requiring manufacturers to install airbags presented an obstacle to the mix of restraints allowed by the federal safety standard.<sup>24</sup>

In finding preemption by conflict, the Court gave weight to the DOT's explanation contained in its litigation brief.<sup>25</sup> The brief stated that the FMVSS embodied the Secretary's policy judgment regarding safety and that state tort actions would stand as an obstacle to federal objectives.<sup>26</sup> The Court justified its reliance on the agency's explanation by pointing to the technical subject matter and the complex and extensive nature of the relevant history, stating that the DOT likely had a unique and thorough understanding of its own regulation and objectives.<sup>27</sup>

The Court further reasoned that "[t]o insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended."<sup>28</sup> The Court then stated that the saving clause foresaw, and did not foreclose, preemption of a state tort action when there was an actual conflict with the federal standard.<sup>29</sup> Furthermore, the preemption provision and the saving clause

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20. *Id.* at 864–65.

21. *Id.* (noting that the FMVSS gave manufacturers a choice of restraints).

22. *Id.* at 865 (explaining that petitioner was injured after her car, which had been equipped with manual belts but lacked airbags, collided with a tree); *id.* at 881 (claiming in her complaint that Honda "had a duty to design, manufacture, distribute and sell a motor vehicle with an effective and safe passive restraint system, including, but not limited to, airbags").

23. *Id.* at 867–68 (finding "no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions").

24. *Id.* at 881.

25. *Id.* at 883.

26. *Id.* at 881 (stating that safety "would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car" (internal quotation marks omitted) (quoting Brief for the United States as Amicus Curiae Supporting Affirmance, *Geier*, 529 U.S. 861 (No. 98-1811), 1999 WL 1045155, at \*25)).

27. *Id.* at 883 (emphasizing that the DOT is "'uniquely qualified' to comprehend the likely impact of state requirements").

28. *Id.* at 885.

29. *Id.* at 870–71 ("[T]his Court has repeatedly 'decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.'" (alteration in original) (quoting *United States v. Locke*, 529 U.S. 89, 106–107 (2000))).

together created a neutral policy regarding conflict preemption.<sup>30</sup> In effect, the Court overcame the traditional presumption against preemption by giving preemptive effect to the DOT's interpretations.

### C. Federal Food and Drug Laws

Congress enacted the Federal Food and Drugs Act in 1906, in response to concerns raised by state regulators, prohibiting the manufacture or shipment of adulterated or misbranded food or drugs in interstate commerce.<sup>31</sup> In 1938, Congress expanded the law to cover medical devices through the Federal Food, Drug, and Cosmetic Act ("FDCA").<sup>32</sup> The FDCA required premarket approval of new drugs, and required the manufacturer to submit an application for approval to the FDA.<sup>33</sup> Once a drug received its initial approval from the FDA, any further changes to its label had to be submitted and approved in a supplemental application.<sup>34</sup> However, the FDA also allowed manufacturers to "add or strengthen an instruction" through a "changes being effected" ("CBE") regulation for any pre-approval additions that were intended to increase the safety of a drug.<sup>35</sup>

In 1962, Congress added a saving clause to the FDCA to protect state sovereignty, establishing that a state law action would only be preempted when in positive conflict with the FDCA.<sup>36</sup> Fourteen years later, Congress enacted the Medical Device Amendments ("MDA") establishing an express preemption provision for medical devices and classifying devices into three categories, with the highest risk devices identified as Class III.<sup>37</sup>

With regard to the FDA's rulemaking authority, Executive Order 13,132 directed agencies to provide states a notice and comment period for proposed regulations that may affect them.<sup>38</sup> In 2006, the FDA promulgated new labeling rules through proper notice-and-comment rulemaking, explaining that the proposed rules would not preempt state tort law.<sup>39</sup> However, after the comment period closed, the FDA inserted a preamble asserting that its regulations preempted state tort claims.<sup>40</sup> The 2006

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30. *Id.* ("But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard actually conflicts with a federal safety standard.").

31. Davis, *supra* note 2, at 1100.

32. *See id.*

33. Wyeth v. Levine, 129 S. Ct. 1187, 1195 (2009).

34. *Id.* at 1196.

35. *Id.* (internal quotation marks omitted) (quoting 21 C.F.R. § 314.70(c)(6)(iii)(C) (2008)).

36. *Id.*

37. *See* Zellmer, *supra* note 1, at 1686, 1690.

38. Sharkey, *supra* note 3, at 253–54 (citing Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 4, 1999)).

39. Wyeth, 129 S. Ct. at 1201.

40. Christen Linke Young, Note, *Agency Preemption Inputs in Riegel v. Medtronic*, 118 YALE L.J. POCKET PART 22, 25 (2008).

preamble presented a dramatic shift toward preempting state laws that deviated from federal labeling regulations and led to the controversial debate on the role of agency safety determinations in the face of common law tort claims.<sup>41</sup> The following cases illustrate how courts have applied the preemption analysis to federal regulations.

1. *Medtronic, Inc. v. Lohr*<sup>42</sup>

The Supreme Court in *Lohr* held that the MDA did not preempt a state tort claim regarding a pacemaker that the FDA had approved as being “substantially equivalent”<sup>43</sup> to other approved devices.<sup>44</sup> In examining the domain expressly preempted by the MDA, the Court found that Congress did not intend to interfere with state remedies or “deprive States of any role in protecting consumers.”<sup>45</sup> It reasoned that the word “requirements” in the MDA referred to additional state regulations but excluded general state common law duties.<sup>46</sup>

Additionally, the Court held that the “substantially equivalent” exception to premarket approval was not intended to ensure the safety of a device, but only established a status quo which included a possibility of defending the device’s design in a state tort suit.<sup>47</sup> The Court concluded that state requirements were only preempted where “the FDA has established ‘specific counterpart regulations or . . . other specific requirements applicable to a particular device.’”<sup>48</sup> In its determination, the majority seemed to apply an impossibility analysis by stating that the MDA did not preempt state rules that merely duplicated the duties imposed by federal law.<sup>49</sup>

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41. See Davis, *supra* note 2, at 1092–93.

42. 518 U.S. 470 (1996).

43. *Id.* at 478 (internal quotation marks omitted) (quoting 21 U.S.C. § 360e(b)(1)(B) (1994)) (explaining devices the FDA considers “substantially equivalent” to approved devices can be marketed without premarket approval in order to ensure timely introduction of improved devices).

44. *Id.* at 481–82 (stating that “no State . . . may establish . . . any requirement which is different from, or in addition to, any requirement . . . which relates to the safety or effectiveness of the device” (internal quotation marks omitted) (quoting 21 U.S.C. § 360k(a) (1994))).

45. *Id.* at 489. The Court relied on the presumption against preemption and congressional intent, “‘the ultimate touchstone’ in every pre-emption case.” *Id.* at 485 (first alteration in original) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

46. *Id.* at 489 (“[Requirements refer to] device-specific enactments of positive law . . . not the application of general rules of common law by judges and juries.”).

47. *Id.* at 494 (“There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents.”).

48. *Id.* at 498 (alteration in original) (quoting 21 C.F.R. § 808.1(d) (1995)); see also *id.* at 501 (“The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question . . .”).

49. See *id.* at 495 (“[T]he state requirement is not pre-empted unless it is ‘different from, or in addition to,’ the federal requirement.” (quoting § 360k(a)(1))).

## 2. *Riegel v. Medtronic, Inc.*<sup>50</sup>

In *Riegel*, the Supreme Court held that a state tort claim regarding a failed FDA-approved Class III catheter was preempted by the MDA as imposing state requirements that differed from, or added to, federal requirements.<sup>51</sup> The Court distinguished the catheter from the pacemaker in *Lohr* by finding that premarket approval imposed requirements under the MDA.<sup>52</sup> Whereas *Lohr* dealt with a device that only received an equivalency review, the opinion emphasized that premarket approval was a rigorous device-specific safety review that permitted almost no deviations from the approved specifications.<sup>53</sup> The Court therefore held that the state tort claim, requiring the catheter to be safer but less effective, was preempted by the MDA.<sup>54</sup>

## II. *WYETH V. LEVINE*<sup>55</sup>

### A. *Facts*

On April 7, 2000, Diana Levine received the drug Phenergan by the IV-push method for treatment of migraine-related nausea.<sup>56</sup> Phenergan is an antihistamine manufactured by Wyeth Pharmaceuticals for the treatment of nausea.<sup>57</sup> The drug can be administered intramuscularly or intravenously.<sup>58</sup> Intravenous administration can occur through the IV-push method, which involves a forced delivery of the drug using a syringe, or the IV-drip method, which slowly drips a mix of the drug and saline solution from an intravenous bag into the vein.<sup>59</sup> Phenergan is corrosive, and causes gangrene upon contact with arterial blood.<sup>60</sup> Of the two intravenous methods, IV-push creates a higher probability of gangrene because of the risk of intra-arterial injection.<sup>61</sup>

The warning label for Phenergan initially met FDA standards in 1955 and continued to comply in its supplemental applications.<sup>62</sup> In 1988, Wyeth submitted a revised warning label in response to the FDA's suggestion of a different warning regarding the risks of intra-arterial in-

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50. 128 S. Ct. 999 (2008).

51. *Id.* at 1011.

52. *Id.* at 1007.

53. *Id.* (stating that premarket approval is only given to devices that the FDA has determined as providing "a reasonable assurance of safety and effectiveness").

54. *Id.* at 1008.

55. 129 S. Ct. 1187 (2009).

56. *Id.* at 1191. Ms. Levine had received the drug on previous visits to her local clinic for treatment of migraine headaches. *Id.*

57. *Id.* ("Phenergan is Wyeth's brand name for promethazine hydrochloride.").

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 1191-92.

62. *Id.* at 1192. The FDA approved the use of Phenergan in 1955 and again in supplemental new drug applications in 1973 and 1976. *Id.*

jection.<sup>63</sup> However, in 1998, without responding to Wyeth's 1988 submission, the FDA approved Wyeth's 1981 supplemental application and directed Wyeth to keep its then current label.<sup>64</sup>

Levine had initially received Phenergan through intramuscular injections on previous visits for her migraine.<sup>65</sup> However, the IV-push method was used on April 7 after an ineffective treatment earlier that day.<sup>66</sup> Following the treatment, Phenergan was accidentally released into Levine's artery.<sup>67</sup> As a result, Levine developed gangrene, and doctors were eventually forced to amputate her right arm.<sup>68</sup>

### *B. Procedural History*

Levine sued Wyeth under Vermont's state product liability claims of negligence and strict liability.<sup>69</sup> Levine alleged that Wyeth failed to warn clinicians to use the IV-drip method.<sup>70</sup> Although Phenergan's label did warn against intra-arterial injection, it did not specifically warn against the IV-push method.<sup>71</sup> Wyeth filed a motion for summary judgment, arguing that federal law preempted the state failure-to-warn claims because the FDA had approved Phenergan's warning label.<sup>72</sup>

The Vermont trial court held the state law claims were not preempted by federal law because Levine's claims did not conflict with FDA regulations.<sup>73</sup> Under FDA regulations,<sup>74</sup> a manufacturer could strengthen its warning label without first attaining FDA approval.<sup>75</sup> The jury found Wyeth negligent for failing to provide adequate warnings about the risks involved with IV-push administration of Phenergan, even

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63. *Id.* (explaining that after submitting a third supplemental application in 1981 in response to a new FDA rule, Wyeth began corresponding with the FDA regarding its submission and in 1987, the FDA suggested a revision).

64. *Id.* (stating that the FDA made a few changes to Phenergan's label that were unrelated to intra-arterial injection then instructed Wyeth to "[r]etain verbiage in current label" (alteration in original) (internal quotation marks omitted)).

65. *Id.* at 1191.

66. *Id.*

67. *Id.* ("Phenergan entered Levine's artery, either because the needle penetrated an artery directly or because the drug escaped from the vein into surrounding tissue . . . where it came in contact with arterial blood.").

68. *Id.* ("[D]octors amputated first her right hand and then her entire forearm. In addition to her pain and suffering, Levine incurred substantial medical expenses and the loss of her livelihood as a professional musician.").

69. *Id.*

70. *Id.* at 1191-92.

71. *Id.* The warning stated in part: "Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection." *Id.* at 1191 n.1 (internal quotation marks omitted).

72. *Id.* at 1192 (contending that there was an "actual conflict between a specific FDA order" and Levine's claim (internal quotation marks omitted)).

73. *Id.* at 1192-93.

74. *Id.* at 1196 (referencing the "changes being effected" ("CBE") regulation requiring manufacturers to change its label as new information becomes available).

75. *Id.* at 1193. The trial court had a record of at least twenty amputation reports since the 1960s. *Id.*



if it had complied with FDA labeling requirements.<sup>76</sup> The jury compensated Levine for the amputation of her arm and the Vermont Supreme Court affirmed, concluding that the federal FDA requirements created “a floor, not a ceiling, for state regulation.”<sup>77</sup>

### C. Majority

In a 6–3 decision authored by Justice Stevens, the U.S. Supreme Court affirmed.<sup>78</sup> The Court employed both an impossibility analysis and an obstacle analysis to conclude that Levine’s state law claims were not preempted by federal law.<sup>79</sup> In reaching its decision, the Court relied on *Lohr*’s fundamental principles of congressional purpose and presumption against preemption.<sup>80</sup>

First, in rejecting Wyeth’s impossibility argument, the Court reasoned that the CBE’s newly acquired information provision was not strictly limited to new information, but also included any new *analyses* of data that the FDA had already considered.<sup>81</sup> The Court found that Wyeth had a duty to add to the warning when it became aware of the risk of gangrene from IV-push injection of Phenergan.<sup>82</sup> Therefore, it was not impossible for Wyeth to add to the warning while still complying with federal law.<sup>83</sup> Furthermore, although the FDA could have subsequently rejected the change, there was no evidence that the FDA would not have allowed for a stronger warning.<sup>84</sup>

Next, the Court rejected Wyeth’s argument that complying with the state-law duty “would obstruct the purposes and objectives” of the

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76. *Id.* (stating that state tort liability “would not obstruct the FDA’s work because the agency had paid no more than passing attention to the question whether to warn against IV-push administration of Phenergan”).

77. *Id.* (agreeing with the trial court that “state law serves a compensatory function distinct from federal regulation”).

78. *Id.* at 1190, 1204.

79. *Id.* at 1204 (concluding that it was not impossible for Wyeth to comply with both state and federal laws, and that the state claims did not “stand as an obstacle to the accomplishment of Congress’ purposes in the FDCA”).

80. *Id.* at 1194–95 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

81. *Id.* (rejecting Wyeth’s argument that unilaterally adding a warning would have subjected it to misbranding liability).

82. *Id.* at 1197–98 (emphasizing that Wyeth had knowledge of at least twenty amputation incidents prior to Levine’s injury); see also Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814) (“Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information.”).

83. *Id.* at 1198–99 (stating that the CBE regulation allowed Wyeth to revise Phenergan’s warning label before receiving FDA approval).

84. *Id.* (concluding that “the FDA had not made an affirmative decision to preserve the IV-push method or intended to prohibit Wyeth from strengthening its warning about IV-push administration”); see also *id.* at 1199 n.5 (noting that although Wyeth had proposed changes to Phenergan’s warning in 1988, these changes were rejected by the FDA because they were not materially different or stronger than the original language of the warning).

FDA.<sup>85</sup> The Court reasoned that the FDCA was enacted to further the protection available to consumers and that the lack of a federal remedy evidenced congressional intent for remedy under state laws.<sup>86</sup> The Court also distinguished prescription drugs from medical devices for which the FDCA contained an express preemption provision.<sup>87</sup> It concluded that Congress's silence on prescription drugs, throughout the seventy years that the FDCA had existed, revealed Congress's intent to preserve state tort actions.<sup>88</sup>

The majority rejected Wyeth's claim that the FDA "must be presumed to have performed a precise balancing of risks and benefits . . . that leaves no room for state law judgments."<sup>89</sup> Wyeth relied on the 2006 FDA regulation preamble containing the FDA's commentary that FDCA regulations created both a floor and a ceiling.<sup>90</sup> However, the Court distinguished the preamble from the weight given to the DOT's explanations in *Geier* as a "mere assertion that state law is an obstacle to achieving its statutory objectives."<sup>91</sup>

Although the majority conceded that an agency's statements explaining the impact of state law on federal objectives was entitled to some deference,<sup>92</sup> it reasoned that the amount given "depend[ed] on [the explanation's] thoroughness, consistency, and persuasiveness."<sup>93</sup> Moreover, the 2006 preamble failed to bear any force, absent the opportunity for states to comment, after the FDA's 2000 notice of proposed rulemaking stated that the rule would "not contain policies that . . . preempt State law."<sup>94</sup> Finally, the Court buttressed its holding with Congress's

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85. *Id.* at 1199.

86. *Id.* ("[Congress] determined that widely available state rights of action provided appropriate relief for injured consumers.").

87. *Id.* at 1200.

88. *Id.* ("Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

89. *Id.*

90. *Id.* ("[The preamble] stated that certain state-law actions, such as those involving failure-to-warn claims, 'threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.'" (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (pt. 2), 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601))).

91. *Id.* at 1201.

92. *Id.* (stating that agency statements are entitled to some deference when "the subject matter is technical[] and the relevant history and background are complex and extensive" (alteration in original) (internal quotation marks omitted) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000))).

93. *Id.* ("Even in such cases, however, we have not deferred to an agency's *conclusion* that state law is pre-empted. Rather, we have attended to an agency's explanation of how state law affects the regulatory scheme. While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'").

94. *Id.* (internal quotation marks omitted) (quoting Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201)).

longstanding view that state laws complement FDA regulations.<sup>95</sup> The FDA's limited resources and the ability of state tort claims to help reveal unknown risks associated with drugs "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times."<sup>96</sup>

#### *D. Justice Thomas's Concurrence*

Justice Thomas concurred with the majority opinion, agreeing that it was not impossible for Wyeth to comply with both federal and state obligations.<sup>97</sup> Aside from the narrower physical impossibility standard, Justice Thomas emphasized that impossibility under the broader direct conflict standard also did not exist because the FDA approval did not shield Wyeth from liability.<sup>98</sup>

However, Justice Thomas criticized the application of the "purposes and objectives" preemption jurisprudence, under the obstacle analysis, as reaching beyond statutory text.<sup>99</sup> Focusing heavily on preserving state sovereignty, he characterized the Supremacy Clause as "accord[ing] pre-emptive effect to *only* those policies that are *actually authorized* by and effectuated through the statutory text."<sup>100</sup> Justice Thomas criticized *Geier* as facilitating "freewheeling, extratextual, and broad evaluations" of federal law by relying on agency explanations instead of the text of the saving clause.<sup>101</sup> Justice Thomas also reprimanded the Court's interpretation of Congress's silence as intent to allow state tort actions.<sup>102</sup> He concluded that although the Court reached the correct decision, the judgment should have been based on the text of the statutory provision rather than the Court's interpretation of congressional inaction.<sup>103</sup>

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95. *Id.* at 1201-02 ("[The FDA] cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims.").

96. *Id.* at 1202 ("The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.").

97. *Id.* at 1204-05 (Thomas, J., concurring). Justice Breyer wrote a separate concurring opinion emphasizing the Court's statement that "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law." *Id.* at 1204. Justice Breyer's concurrence is outside the scope of this Comment.

98. *Id.* at 1209.

99. *Id.* at 1205 ("Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law.").

100. *Id.* at 1216 (emphasis added).

101. *Id.* at 1214, 1217.

102. *Id.* at 1216-17 ("[O]nce the Court shows a willingness to guess at the intent underlying congressional inaction, the Court could just as easily rely on its own perceptions regarding congressional inaction to give unduly broad pre-emptive effect to federal law.").

103. *Id.*:

Certainly, the absence of a statutory provision pre-empting all state tort suits related to approved federal drug labels is pertinent to a finding that such lawsuits are not pre-empted. But the relevance is in the fact that no statute explicitly pre-empts the lawsuits, and not in any inferences that the Court may draw from congressional silence about the motivations or policies underlying Congress'[s] failure to act.

*E. Dissent*

Justice Alito authored the dissenting opinion joined by Chief Justice Roberts and Justice Scalia. The dissent argued that conflict preemption prohibited state tort juries from overriding the FDA's drug safety determinations.<sup>104</sup> Justice Alito argued that Congress's purpose was clear in "authorizing the FDA—not state tort juries—to determine when and under what circumstances a drug is 'safe.'"<sup>105</sup> Justice Alito further reasoned that the FDA had extensively considered the costs and benefits of the IV-push administration of Phenergan.<sup>106</sup> He stated that, as in *Geier*, conflict preemption was not defeated by either a saving clause or the absence of an express preemption provision as long as an actual conflict existed.<sup>107</sup>

Furthermore, Justice Alito rejected the Court's interpretation of the 2006 preamble as having no weight,<sup>108</sup> and instead argued that the FDA's labeling decisions bear the force of law.<sup>109</sup> Under *Geier*, the presumption against preemption and an agency's specific intent to preempt through notice-and-comment rulemaking were not relevant<sup>110</sup> where state tort duties stood in *actual* conflict with federal objectives.<sup>111</sup> Finally, Justice Alito stated that juries were "ill-equipped to perform the FDA's cost-benefit-balancing function."<sup>112</sup> He warned that juries would undermine the drug-labeling function of the FDA and that those benefitting from the drugs would suffer "if juries in all 50 states were free to contradict the FDA's expert determinations."<sup>113</sup>

### III. ANALYSIS

In *Wyeth v. Levine*, the Court properly reemphasized the importance of congressional intent and the presumption against preemption as the "cornerstones" of preemption jurisprudence.<sup>114</sup> In doing so, the Court

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104. *Id.* at 1218–19 (Alito, J., dissenting).

105. *Id.* at 1219–20 ("Neither the FDCA nor its implementing regulations suggest that juries may second-guess the FDA's labeling decisions.").

106. *Id.* at 1222–26 (noting that the FDA cited numerous medical authorities to support IV-push administration of Phenergan and provided specific extensive warnings of the associated risks).

107. *Id.* at 1220–21.

108. *Id.* at 1228 (stating that the FDA has an understanding of how state law could obstruct federal objectives and therefore "can translate these understandings into particularized pre-emptive intentions . . . through statements in regulations, preambles, interpretive statements, and responses to comments" (alteration in original) (internal quotation marks omitted) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996) (Breyer, J., concurring))).

109. *Id.* (citing 21 U.S.C. § 355 (2006)).

110. *Id.* ("It is well within the FDA's discretion to make its labeling decisions through administrative adjudications rather than through less-formal and less-flexible rulemaking proceedings, and we have never previously held that our pre-emption analysis turns on the agency's choice of the latter over the former." (citation omitted)).

111. *Id.* (stating that "pre-emption follows automatically by operation of the *Supremacy Clause*" (emphasis added)).

112. *Id.* at 1229–30 (arguing that juries only see those injured by a drug but never see those who have benefitted from the drug, whereas the FDA's judgments have considered all interests).

113. *Id.* at 1230.

114. *Id.* at 1194–95 (majority opinion).

revamped the significance of a presumption against preemption in an implied conflict preemption analysis. The *Wyeth* decision restored proper weight to saving clauses and clarified the FDA approval debate by rejecting the approval of Phenergan as a conclusive statement of safety.

However, the Court's preamble analysis did not go far enough. A more restrictive analysis of agency views would have led future cases away from the *Geier* decision by requiring strict adherence to the notice-and-comment rulemaking procedures. On a broader level, while the impossibility analysis warrants adherence, the Court's purposes and objectives determinations in its obstacle analysis should be abandoned. Furthermore, a classification of drugs based on their level of risk could help clarify future preemption battles.

#### *A. The Restoration of the Presumption Against Preemption*

Although the presumption against preemption was relevant in *Lohr*, the *Geier* Court failed to consider it in its conflict preemption determination. The *Wyeth* Court's holding, and its reliance on the longstanding principle, signifies the importance of a presumption in all instances of implied preemption and exposes the faulty reasoning in the wrongly decided *Geier* case.

The *Wyeth* dissent misinterprets *Geier*'s focus on actual conflict as making a presumption against preemption irrelevant.<sup>115</sup> Justice Stevens's opinion restores harmony between federal power and state sovereignty by starting with a respect for traditional state powers absent an express preemption provision. By rejecting *Wyeth*'s argument that the presumption should not apply to instances where the federal government has shown to have regulated drug labeling for over a century, the *Wyeth* Court makes clear that the purpose of the principle is driven by a consideration of states as "independent sovereigns in our federal system."<sup>116</sup> Focusing on the cornerstones of preemption, the *Wyeth* Court properly ensured that "the longstanding coexistence of state and federal law in the

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115. See *id.* at 1195 n.3.

116. *Id.* (internal quotation marks omitted) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); see also David A. Dana, *Democratizing the Law of Federal Preemption*, 102 Nw. U. L. REV. 507, 511 (2008):

The federalism-based presumption against preemption suggests, by its very terms, that in preemption cases the courts must balance the potential harm to the efficacy of democratically enacted federal law against the importance of federalism principles rooted in state sovereignty. When the balance is close . . . the court should come down on the side of no preemption.

Matthew S. Reid, Comment, *Vermont Supreme Court Rules That Food and Drug Administration Regulations Do Not Preempt State Failure-to-Warn Claims*: *Levine v. Wyeth*, 4 J. HEALTH & BIOMEDICAL L. 413, 425 (2008):

[H]ealth and safety has traditionally been considered part of the states' police-powers since the founding of the Republic and the attempts of a federal agency to encroach on the traditional legal territory of the states should only occur with the manifest consent of the Congress which is clearly not indicated here.

area of pharmaceutical warning labels would remain intact”<sup>117</sup> and rejected the *Geier* Court’s attempt to undercut this balance.<sup>118</sup>

### *B. The Decision’s Effect on Saving Clauses*

The *Wyeth* Court’s decision to preserve the presumption against preemption principle also gives proper weight to saving clauses. Saving clauses further reflect congressional intent to preserve state powers to protect public health and welfare where a conflict with a federal law does not exist.<sup>119</sup> The *Wyeth* Court’s emphasis on the presumption against preemption—requiring *clear* congressional intent to preempt state remedies—fortifies the general principle behind saving clauses.

The *Geier* Court previously rejected the presumption against preemption, concluding that the existence of both a preemption provision and a saving clause created a neutral policy of preemption.<sup>120</sup> This view, however, undermines Congress’s desire to avoid regulatory gaps left by federal law by allowing for protection through state laws.<sup>121</sup> Whereas preemption provisions, such as those in *Lohr* and *Geier*, are often ambiguous and can result in various delineations of state and federal law boundaries, the presence of a saving clause remains clear in nearly all instances as working to “leave ample room for state law to provide increased protection above the federal regulatory floor.”<sup>122</sup> Furthermore, giving proper effect to saving clauses could work to override the recent deference given to agency interpretations by acting as further evidence of congressional intent to retain state remedies.

The *Wyeth* decision is a step toward both dispelling the “neutral policy” trend of the *Geier* Court and restoring the significance of saving clauses for future cases.<sup>123</sup> The *Wyeth* Court cured the inability of future courts to both narrow an agency’s preemptive scope and create a safe harbor for state law.<sup>124</sup> By utilizing the saving clause to reject the preamble’s preemptive powers, the *Wyeth* Court avoided the risk of “sending

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117. Dawn Goulet, Consumer News, *LinkLine Decision Puts the Squeeze on the Price Squeeze Theory of Liability*, 21 LOY. CONSUMER L. REV. 429, 434 (2009).

118. See Reid, *supra* note 116 (“The court accurately resolved the issue in a manner consistent with judicial precedent, legislative history, and basic principles of federalism.”).

119. See Zellmer, *supra* note 1, at 1660.

120. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000).

121. See Zellmer, *supra* note 1, at 1668.

122. *Id.* at 1660.

123. See *id.* at 1702; see also *id.* at 1732 (“[G]iving savings clauses appropriate weight honors congressional choices, avoids regulatory gaps, fosters innovative measures to protect human health . . . and enhances institutional competency by empowering governments at all levels to protect the public at appropriate scales.”).

124. Young, *supra* note 40, at 26 (“If the Court relies on the agency’s preamble in *Wyeth* and holds the state law preempted, then successive majorities will have frowned upon the FDA’s attempts to *limit* preemption in *Riegel*, while welcoming its attempts to *expand* it in *Wyeth*. In the hands of the Court, agency action defining preemptory authority risks becoming a one-way ratchet—fully applicable in the service of strong federal preemption, but unable to narrow the preemptive scope when it seeks to create a safe harbor for state law.”).

mixed messages to federal agencies—granting them authority to assert broad preemption, but skeptically reviewing any attempt to narrow preemptive scope.”<sup>125</sup>

Furthermore, giving proper weight to the presence of a saving clause will never act to unduly bar valid determinations of conflict preemption. The Supremacy Clause ensures that actual conflicts between federal and state laws will lead to the preemption of those state laws.<sup>126</sup>

### C. Clarification of FDA Approval and Manufacturers’ Responsibilities

The *Wyeth* Court’s holding, despite Phenergan’s FDA approval, rightfully casts *Riegel* “in the narrow light it deserves, as a case governing only the limited group of Class III devices that receive the most rigorous FDA scrutiny available under federal law.”<sup>127</sup> With its decision, the *Wyeth* Court affirmed the notion that FDA approval of a drug is not based on the optimal safety of a drug, but based only on the information the FDA receives from the drug’s manufacturer.<sup>128</sup>

For close to fifty years, it has been the manufacturers’ responsibility to prove the safety of a drug in order to distribute the drug, instead of the FDA’s responsibility to prove a drug’s harm in order to keep it out of the market.<sup>129</sup> With a shift in the burden of proof, courts cannot assume that the FDA has retained the same level of incentive or burden to actively discover new risks posed by a drug. The FDA continues to be largely dependent on the information provided by each manufacturer, and removing the manufacturers’ incentive to maintain the safety of the drugs—by awarding them immunity in tort claims—would result in less safe drugs.<sup>130</sup> The FDA’s report stating “the budget and staff of the [FDA] are inadequate to permit the discharge of its existing responsibilities for the protection of the American public”<sup>131</sup> further supports this view.<sup>132</sup> The *Wyeth* Court’s emphasis on the manufacturers’ responsibili-

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125. *Id.* at 23 (pointing out the problematic implications of this outcome); *see also id.* at 25 (“[T]he . . . savings regulation has the general effect of limiting preemption, while the 2006 language carves out the widest possible preemptive space.”).

126. Zellmer, *supra* note 1, at 1733.

127. *Id.* at 1696.

128. *See id.* at 1694–95.

129. *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009) (referencing the 1962 amendment to the FDCA shifting the burden of proof to the manufacturer).

130. Reid, *supra* note 116; *see also* Dawn Goulet, Consumer News, *Supporters and Opponents of Federal Preemption Take Sides, Anticipate High Court’s Ruling on Third FDA Preemption Case This Year*, 21 LOY. CONSUMER L. REV. 96, 104 (2008) (“Congress never intended that FDA approval give blank immunity to manufacturers from liability for injuries caused by their products.” (internal quotation marks omitted) (quoting *Kennedy, Pallone Eye Legislation to Undo Preemption Ruling*, FDA WK., Feb. 29, 2008, available at 2008 WLNR 4025500)).

131. *Wyeth*, 129 S. Ct. at 1202 n.11 (internal quotation marks omitted) (quoting CITIZENS ADVISORY COMM. ON THE FDA, REPORT TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE, H.R. Doc. No. 84-227, at 53 (1955)).

132. *See Goulet, supra* note 130:

The [FDA’s own science] board ‘concluded that science at the FDA is in a precarious position,’ and the agency ‘is not positioned to meet the current or emerging regulatory re-

ty of maintaining adequate warning labels appropriately rejects the treatment of FDA approval as a conclusive statement of safety.<sup>133</sup>

Although *Wyeth* did not address *Riegel*'s decision to include state tort actions as falling within preemption, it restores the *Lohr* Court's favorable view of state tort claims. Though the *Wyeth* dissent argued that the FDA's safety determinations should not be questioned, allowing state tort judgments to proceed will *increase* consumer protection. As the *Wyeth* Court stated, state tort suits often bring to light unknown dangers of FDA approved drugs<sup>134</sup> and motivate manufacturers to disclose those risks.<sup>135</sup> If FDA approval were to shield drug manufacturers from common-law liabilities, manufacturers might misrepresent information to the FDA in order to attain approval.<sup>136</sup> Tort remedies, however, provide manufacturers incentives to avoid liability by actively analyzing new risks and working to improve the safety of their products.<sup>137</sup>

#### *D. The Effect of the Wyeth Court's Interpretation of the 2006 Preamble*

*Wyeth* rejected the preemptive effect of the 2006 preamble as meriting no deference. However, the Court's mere comparison to the DOT's explanations in *Geier* fell short of setting the necessary precedent of requiring a clear congressional intent for preemption. The Court should have used the opportunity to invalidate *Geier*'s dependence on agency explanation by strictly relying on statutory text in its preemption analysis.

The *Wyeth* Court acknowledged that certain agency views could properly preempt state action through a thorough, consistent, and persuasive explanation regarding the obstacle that state tort actions would impose on federal objectives.<sup>138</sup> The Court further noted that while "agencies have no special authority to pronounce on pre-emption absent delegation by Congress,"<sup>139</sup> weight is given to agency views when "the subject matter is technical[,] and the relevant history and background are complex and extensive."<sup>140</sup> By merely distinguishing the case from *Gei-*

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sponsibilities.' It cited two resources for this deficiency: 1) demands on the FDA have soared, and 2) resources allocated to the agency have not increased in proportion to those demands.

(quoting SUBCOMM. ON SCI. & TECH., FDA, FDA SCIENCE AND MISSION AT RISK 2 (2007), [http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4365b1\\_02\\_04\\_Subcommittee%20Report%20on%20Science%20and%20Technol.pdf](http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4365b1_02_04_Subcommittee%20Report%20on%20Science%20and%20Technol.pdf)).

133. See Zellmer, *supra* note 1, at 1694–95.

134. See Goulet, *supra* note 117, at 436 (praising the benefits of a dual system and recognizing that state tort suits "may motivate injured persons to come forward with information" (internal quotation marks omitted) (quoting *Wyeth*, 129 S. Ct. at 1202)).

135. *Wyeth*, 129 S. Ct. at 1202.

136. See Sharkey, *supra* note 3, at 238.

137. See Zellmer, *supra* note 1, at 1674.

138. *Wyeth*, 129 S. Ct. at 1201.

139. *Id.*

140. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000).



er, the *Wyeth* Court failed to drive future decisions away from the recent controversy regarding agency preemption determinations.<sup>141</sup>

Under Executive Order 12,988, agencies must clearly specify the preemptive effect of a law.<sup>142</sup> Furthermore, under Executive Order 13,132, agencies must provide states notice and an opportunity to comment on regulations that may affect them.<sup>143</sup> This notice-and-comment rulemaking, laid out in the Administrative Procedure Act, protects states by ensuring that they are consulted for any preemption decisions.<sup>144</sup> Although Congress entrusted agencies with the authority to regulate, agencies *must* adhere to the specificity and notice-and-rulemaking requirements in order to ensure that regulations reflect congressional intent.<sup>145</sup> Furthermore, these procedures prevent a boundless doctrine of implied conflict preemption<sup>146</sup> and honor the crucial presumption against preemption when dealing with agency regulations.<sup>147</sup>

Applying the above to *Geier*, the Court should have ended its analysis when it found that the FMVSS lacked any specific intent to preempt state tort actions. Because agencies have the ability to make their intentions clear, courts should not encourage agencies<sup>148</sup> to deviate from these procedures by taking into account an agency's views about how a state action would create an obstacle to federal purposes and objectives. By developing one strict standard, courts can avoid the debate regarding the amount of deference given to agency views.

Additionally, any trend validating the *Geier* decision is troubling. Allowing agencies to self-empower themselves to preempt state laws without going through the proper procedures would completely bar a private right of action.<sup>149</sup> While agencies can set forth rules under their delegated authority, they lack the power to allow private rights of action.<sup>150</sup> This result, coupled with an absence of a federal remedy under the FDCA, would be at extreme odds with the two cornerstones of the preemption jurisprudence. Congress, in its expansion of the FDA's regulatory authority, did not include a private right of action for damages in

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141. See Sharkey, *supra* note 3, at 254.

142. *Id.* at 242 (citing Exec. Order No. 12,988, 61 Fed. Reg. 4729, 4731 (Feb. 5, 1996)).

143. *Id.* at 254–55 (citing Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,256 (Aug. 4, 1999)).

144. See *id.* at 254.

145. *Geier*, 529 U.S. at 907 (Stevens, J., dissenting) (“[T]he power of pre-emption [is] squarely in the hands of Congress.”).

146. Sharkey, *supra* note 3, at 258 (“Agency preemption preambles represent the latest manifestation of a broader trend of the increasing federalization of law governing products regulated in a national market.”).

147. See *Geier*, 529 U.S. at 907 (Stevens, J., dissenting).

148. Sharkey, *supra* note 3, at 254 (stating that “agencies are thumbing their noses at these congressional and executive mandates”).

149. See *id.* at 242.

150. *Id.* at 248 (recognizing that “[a]gencies may play the sorcerer’s apprentice but not the sorcerer himself” (alteration in original) (internal quotation marks omitted) (quoting Alexander v. Sandoval, 532 U.S. 275, 291 (2001))).

order to maintain the harmonious relationship between state and federal regulations.<sup>151</sup> Barring remedy through state tort actions would contradict Congress's purpose<sup>152</sup> of having enacted the FDCA and would deny the presumption against preemption *without* the required clear and manifest purpose of Congress.<sup>153</sup> Because agencies, unlike Congress, are not elected to represent the interests of states, their broad preemptive power must be strictly regulated in order to prevent unjust results.

*E. A Necessary Abandonment of the "Purposes and Objectives" Obstacle Analysis*

The concerns raised in permitting agencies to make their own preemption determinations call for the abandonment of the Court's purposes and objectives preemption jurisprudence employed in the obstacle analysis. As Justice Thomas' concurrence in *Wyeth* states, the broad approach to the purposes and objectives determination has allowed courts to make their own judgments outside of what has been clearly expressed by the statutory text.<sup>154</sup>

The Tenth Amendment states that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively."<sup>155</sup> In order to abide by the Constitution and preserve this balance of power, the Supremacy Clause and its preemption doctrine should only be applied to federal laws that are "made in Pursuance" of the Constitution.<sup>156</sup> Therefore, it follows that "pre-emptive effect be given only those to federal standards and policies that are set forth in, or necessarily follow from, the statutory text."<sup>157</sup>

In order to better respect the purpose of Congress as the touchstone of the preemption inquiry, the broad purposes and objectives determination, found in the *Geier* decision and followed by the *Wyeth* Court, should be abandoned. The *Geier* Court's reliance on the DOT's statements to concoct a federal objective of gradually phasing in a variety of passive restraints was plainly at odds with the expressed purpose of the

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151. See Diana Rabeh, Issues in the Third Circuit, *Is Preemption Right for You?: The Third Circuit Applies Preemption to a Misleading Drug Advertisement Claim in Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, 53 VILL. L. REV. 743, 749–51 (2008) (finding that "a private right of action for damages was 'unnecessary' because a 'common law right of action exists'" (quoting Louis M. Bograd, *Taking on Big Pharma—and the FDA*, TRIAL, Mar. 2007, at 30, 30)).

152. Davis, *supra* note 2, at 1139 ("[T]he objective of the food and drug laws has been clear: to protect the public health and safety from adulterated and misbranded drugs.").

153. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

154. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1212 (2009) (Thomas, J., concurring).

155. U.S. CONST. amend. X.

156. *Wyeth*, 129 S. Ct. at 1206 (Thomas, J., concurring) (internal quotation marks omitted) (quoting U.S. CONST. art. VI, cl. 2).

157. *Id.* at 1207.

Safety Act "to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents."<sup>158</sup>

Future compliance with the *Wyeth* Court's purposes and objectives jurisprudence will only lead to additional unconstitutional invalidations of state laws. Although saving clauses are in place to limit the Court's broad determinations of federal objectives, the *Geier* decision serves as a warning that saving clauses are often overridden. Furthermore, in the absence of the obstacle analysis, the impossibility analysis will continue to properly preempt the necessary state laws. Expanding the impossibility analysis to include both a narrower physical impossibility and a broader conflict impossibility will also allow courts to preempt state laws that would impose contradictory duties<sup>159</sup> even if a manufacturer could comply with both laws. This standard will preserve the holdings of *Lohr* and *Wyeth* while appropriately directing future decisions away from *Geier*. Basing implied preemption on the impossibility analysis would guarantee that the presumption against preemption will only be overridden when the proper burden is met.

*F. An Additional Suggestion to Balance Manufacturer Concerns in the Preemption Battle*

Requiring agencies to adhere to notice-and-comment rulemaking in their preemption decisions, while abolishing the obstacle analysis, will rightfully swing the preemption jurisprudence toward state sovereignty. However, Congress has entrusted the FDA to regulate the safety and effectiveness of drugs as "[t]he centerpiece of risk management,"<sup>160</sup> and these changes will undoubtedly bring harsh criticisms.

As pointed out by the *Wyeth* dissent, the FDA makes safety determinations based on long-term costs and benefits, and the interests of all potential users.<sup>161</sup> The dissent warns that if every state were "free to contradict the FDA's expert determinations," others who would have benefited from the drug would suffer.<sup>162</sup> Manufacturers could be doing all they should to investigate potential new risks. Subjecting them to a myriad of state laws could shift their focus from improving their drugs to constantly searching for potential new risks.

These concerns, in light of the proposed changes, require the establishment of a more instructive standard for prescription drugs. Like the MDA classification of medical devices, prescription drugs should be

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158. See *id.* at 1215 (internal quotation marks omitted) (quoting National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1381 (1988) (repealed 1994)).

159. See *id.* at 1209.

160. *Id.* at 1219 (alteration in original) (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601)).

161. *Id.* at 1230 (Alito, J., dissenting).

162. *Id.*

classified based on the level of risk they pose to the public. Class III drugs would require satisfaction of the most rigorous standards, and the FDA should require the manufacturers of those drugs to report even individual cases of injury for immediate risk analysis and warning update. Placing drugs such as Phenergan into the Class III category would provide courts with evidence of having complied with the most rigorous safety standards. While the addition of a classification system for prescription drugs would not necessarily act to bar state suits, it would set stricter standards for Class III drugs and allow manufacturers to point to their compliance to reduce or eliminate their liability in tort suits such as *Ms. Levine's*.

### CONCLUSION

The battle between federal preemption and state sovereignty, in matters of safety regulations, has been the center of an ongoing debate. In examining the preemption of a state tort action regarding the safety of a prescription drug, the *Wyeth* Court followed the impossibility and the obstacle analyses employed in prior implied preemption cases. The decision in *Wyeth* properly reemphasized the significance of the presumption against preemption and the need for clear congressional intent to preempt. By doing so, the Court gave weight to traditional state police powers and restored the meaning of saving clauses, which the *Geier* Court had previously stripped.

However, the Court's preamble analysis did not go far enough. The decision reveals the need for a stricter requirement of adhering to the notice-and-comment rulemaking procedures to reflect congressional intent. Furthermore, the *Wyeth* Court's following of *Geier's* "purposes and objectives" jurisprudence raises concerns about the textual validity of a federal objective determination. Therefore, this Comment suggests that the Court fully abandon the obstacle analysis. In doing so, the Court should expand the impossibility analysis to encompass both physical impossibility and conflict impossibility, to assure that implied preemption will adequately preempt state laws that impose a contradictory duty. In light of these changes, this Comment suggests the classification of drugs to provide a safeguard for manufacturers in future state tort actions.

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